UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,480	10/23/2003	Silviu Itescu	0575/66602-B/JPW/BJA	2572

7590 05/09/2008

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,480	ITESCU, SILVIU	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-37,43,46,47,49-51 and 53-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/1//08 and 10/23/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 11 February 2008 has been entered in full. Claims 35, 36, 46, 47, 49, 50 are amended. Claims 53-57 are added. Claims 1-34, 38-42, 44, 45, 48, and 52 are cancelled.

After further consideration by the Examiner, the species of administration and disorder of tissue as set forth in the restriction requirements of 18 October 2006 and 27 March 2007 are hereby *withdrawn*. Claim 50 is rejoined.

Claims 35-37, 43, 46, 47, 49, 50, 51, and 53-57 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to the drawings at pg 4 of the previous Office Action (08 August 2007) is *withdrawn* in view of the newly submitted Figure 26 (11 February 2008).

2. The objection to the specification at page 4 of the previous Office Action (08 August 2007) is *withdrawn* in view of the amended specification (11 February 2008).

3. The objection to claim 35 at pages 4-5 of the previous Office Action (08 August 2007) is *withdrawn* in view of the amended claim (11 February 2008).

4. The provisional rejections of claims 45, 48, and 52 under nonstatutory obviousness-type double patenting as set forth at pages 5-7 of the previous Office Action (08 August 2008) are *withdrawn* in view of the cancelled claims (11 February 2008).

5. The rejection of claims 35-37, 43, 49, and 51 under 35 U.S.C. § 112, first paragraph (written description) as set forth at pages 7-9 of the previous Office Action (08 August 2007) is *withdrawn* in view of the amended claims and cancelled claims (11 February 2008).

6. The rejection of claims 35-37, 43, 45-49, and 51-52 under 35 U.S.C. § 112, first paragraph (scope of enablement) as set forth at pages 9-12 of the previous Office Action (08 August 2007) is *withdrawn* in view of the amended and cancelled claims (11 February 2008).

7. The rejection of claims 35-36, 45-46, and 52 under 35 U.S.C. § 102(e) as set forth at pages 12-13 of the previous Office Action (08 August 2007) is *withdrawn* in view of the amended claims and cancelled claims (11 February 2008).

8. The supplemental information disclosure statement filed on 11 February 2008 has been considered.

Double Patenting

9. Claims 35-36 and 53-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 85 of copending Application No. 10/512,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a disorder of a tissue involving apoptosis of tissue cells comprising administering an agent effective to inhibit apoptosis of the cells within the tissue. The basis for this provisional rejection is set forth for claims 35-36 and 45 at pages 5-6 of the previous Office Action (08 August 2007).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

At page 13 of the Response of 11 February 2008, Applicant requests that if this is the sole remaining ground of rejection, the Examiner withdraw the rejection and allow the claims to issue.

The rejection is maintained and held in abeyance until all other issues are resolved. However, Applicant is encouraged to submit a terminal disclaimer at Applicant's earliest convenience.

10. Claims 35-37, 43, 46-47, 49, 50, 51 and 53-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 69, 77-78, 82-84 of copending Application No. 11/234,879. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a disorder comprising administering stromal-derived factor-1. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The basis for this provisional rejection is set forth for claims 35-37, 43, 45-49, and 51-52 at pages 6-7 of the previous Office Action (08 August 2007).

At page 13 of the Response of 11 February 2008, Applicant requests that if this is the sole remaining ground of rejection, the Examiner withdraw the rejection and allow the claims to issue.

The rejection is maintained and held in abeyance until all other issues are resolved. However, Applicant is encouraged to submit a terminal disclaimer at Applicant's earliest convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

> such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 35-37, 43, 46, 49-51, 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson, BE (US 2002/0094327; priority to 05 November 2000) in view of Hung et al. (US 2003/0171294; priority to 13 August 1999).

Peterson teaches that modulating the level of SDF-1α protein in a target tissue can selectively direct migration of pluripotent stem cells to the target tissue (page 1, [0006]). Peterson continues to disclose that "[b]y increasing the number of pluripotent stem cells that traffic to the target tissue, the rate of tissue repair can be increased because there will be a greater number of pluripotent stem cells in the target tissue that can differentiate into cells which can repopulate and partially or wholly restore the normal function of the damaged tissue" (page 1, [0006]). Peterson teach a method of targeting a pluripotent stem cell to a target tissue comprising introducing the SDF-1α protein into the mammalian subject in order to increase the concentration of SDF-1α in the target tissue (page 1, [0007]). Peterson discloses that SDF-1α can be introduced by intravenous injection, intraarterial injection, injection into the target tissue, intrahepatic injection, or by introducing a matrix impregnated with SDF-1α (page 1, [0007]). Peterson teaches that target tissues can be any within a mammalian subject, such as heart (page 8, column 2, [0063]). Peterson also discloses that target cells for use in the invention can include any cell in or that migrates to a target tissue (page 8, column 2, [0063]). It is noted that a compound and all of its properties are inseparable; they are one and the same thing (see *In re Papesch*, CCPA 137 USPQ 43; *In re Swinehart and Sfiligoj*, 169 USPQ 226 (CCPA 1971); *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)).

Peterson et al. does not teach that SDF-1α is administered to the heart intramyocardially or intracoronarily.

Hung et al. teach the intramyocardial and intracoronary administration of angiogenic factors, such as fibroblast growth factor (FGF), to the heart (page 2, paragraphs 9-10; page 4, paragraph 22; page 5, paragraph 34; Figure 8).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of administering of SDF-1α to heart tissue as taught by Peterson by utilizing intramyocardial or intracoronary administration as taught by Hung et al. The person of ordinary skill in the art would have been motivated to make that modification in order to localize cell migration/differentiation and tissue repair (see for example, Hung et al. page 1, [0007]). The person of ordinary skill in the art reasonably would have expected success because similar proteins and agents were already being intramyocardially and intracoronarily administered to the heart at the time the invention was made. Therefore, the claimed invention as a whole was clearly *prima facie* obvious over the prior art.

11. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson, BE (US 2002/0094327; priority to 05 November 2000) and Hung et al. (US 2003/0171294; priority to 13 August 1999) as applied to claims 35-37, 43, 46, 49-51, 53-57 above, and further in view of Rempel et al. (Clin Can Res 6: 102-111, 2000).

The teachings of Peterson and Hung et al. are set forth above.

Peterson and Hung et al. do not teach the administration of SDF-1β.

Rempel et al. teaches that the SDF-1 gene encodes two isoforms, SDF-1α and SDF-1β, that arise from alternative splicing (page 102, column 2, last paragraph). Rempel et al. also

disclose that these isoforms differ only in that SDF-1β contains four additional 3' amino acids (page 102, column 2, last paragraph).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of intramyocardially or intracoronarily administering SDF-1α to heart tissue as taught by Peterson and Hung et al. by substituting SDF-1α with SDF-1β as taught by Rempel et al. Since Rempel et al. teach that SDF-1α and SDF-1β are isoforms encoded from the SDF-1 gene and that SDF-1β only contains four additional amino acids as compared to SDF-1α, it would have been obvious to one skilled in the art to substitute the utilization of SDF-1α for the SDF-1β to achieve the predictable result of treating a subject suffering from a heart disorder.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
05 May 2008

/Bridget E Bunner/
Primary Examiner, Art Unit 1647